APR 2 6 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k123271

Company / Contact Person

Karen Lee
Regulatory Affairs Specialist
Thermo Fisher Scientific, Clinical Diagnostics Division
46360 Fremont Blvd.
Fremont, CA 94538
Phone: (510) 979-5000 x31814
Fax: (510) 979-5422
E-mail: karen.lee@thermofisher.com

Date Prepared

October 17, 2012

Regulatory Declarations

Common / Usual Name	Phenobarbital Assay
Trade / Proprietary Name	Abbott Phenobarbital Assay
Classification Regulation	21 CFR 862.3660
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	DLZ

Intended Use

Phenobarbital Assay

The Abbott Phenobarbital assay is for in vitro diagnostic use for the quantitative measurement of phenobarbital in human serum or plasma on the ARCHITECT cSystems. The measurements obtained are used in the diagnosis and treatment of phenobarbital overdose and in monitoring levels of phenobarbital to help ensure appropriate therapy.

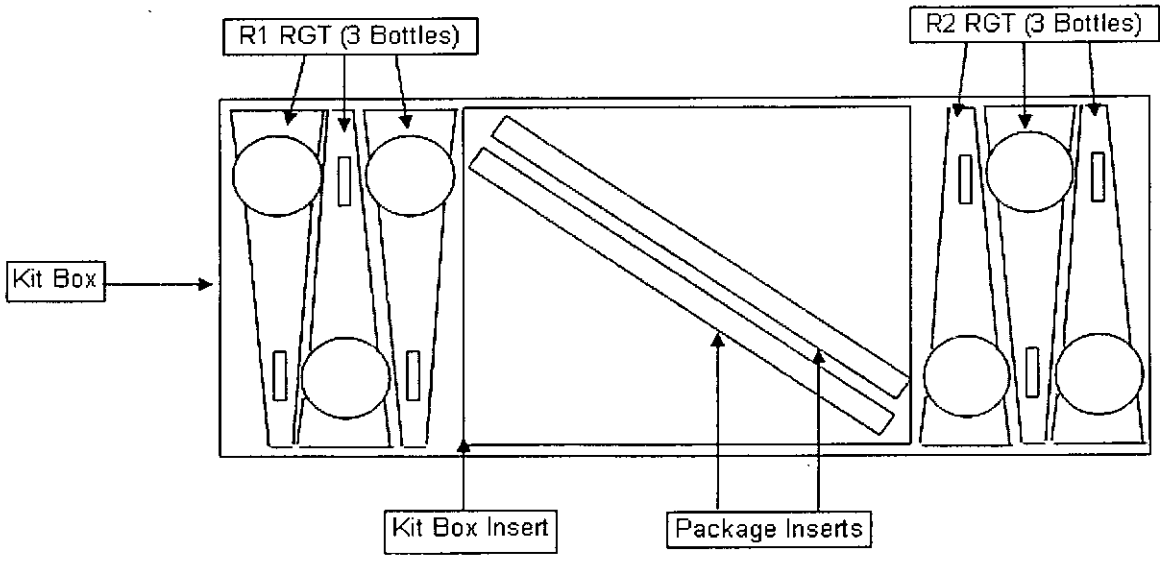
Legally Marketed Device to Which Equivalency is Claimed

The Phenobarbital Assay is substantially equivalent to the previously cleared Abbott Aeroset® Phenobarbital Assay (k993031).

Device Description

The Phenobarbital Assay kit is supplied ready-to-use in liquid form, for storage at 2 to 8°C. Each Phenobarbital Assay kit is packaged in a rectangular cardboard box divided into three sections. One section will contain three bottles of Antibody Reagent (R1), one section will contain three bottles of Microparticle Reagent (R2), and the last section will contain the package insert. Each kit is sufficient for 300 tests. The configuration is as follows:

Component	Description	Configuration
R1 Antibody Reagent	<2.0% Anti-Phenobarbital monoclonal antibody (mouse) in Tris buffer and <0.09% sodium azide as preservative.	3 x 23 mL
R2 Microparticle Reagent	<1.0% Phenobarbital-coated microparticles containing <0.09% sodium azide as preservative.	3 x 9 mL



Comparison of Technological Characteristics

Comparison	Proposed Device	Predicate
Proprietary Name	Abbott Phenobarbital Assay	Abbott Aeroset® Phenobarbital Assay (k993031)
Intended Use	The Phenobarbital assay is used for the in vitro quantitative measurement of phenobarbital in human serum or plasma on the ARCHITECT cSystems.	The assay is intended for use in the quantitative analysis of Phenobarbital in human serum or plasma.
Test Principle	The Phenobarbital assay is a homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) used for the analysis of phenobarbital in serum or plasma. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the phenobarbital antibody reagent. The phenobarbital-coated microparticle reagent is rapidly agglutinated in the presence of the anti-phenobarbital antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically, and is directly proportional to the rate of agglutination of the particles. When a sample containing phenobarbital is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained, with maximum rate of agglutination at the lowest phenobarbital concentration and the lowest agglutination rate at the highest phenobarbital concentration.	The Phenobarbital assay is a homogeneous enzyme immunoassay technique used for the analysis of phenobarbital in biological fluids. The assay is based on competition for antibody binding sites between the analyte drug in the specimen and exogenous drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH). Since G6PDH activity decreases upon binding to the antibody, the concentration of drug in the specimen can be measured in terms of enzyme activity. Active G6PDH reduces nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophtometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.
Sample Matrix	Human Serum or Human Plasma	Human Serum or Human Plasma
Reagent	Liquid Ready-to-Use (Antibody reagent, Phenobarbital-coated microparticle reagent)	Liquid Ready-to-Use (Antibody reagent, Phenobarbital-labeled enzyme reagent)
Storage	2-8°C	2-8°C
Calibrator	Liquid Ready-to-Use, six levels (0.0, 5.0, 10.0, 20.0, 40.0, and 80.0 µg/mL)	Liquid Ready-to-Use, six levels (0.0, 5.0, 10.0, 20.0, 40.0, and 80.0 µg/mL)
Assay Range	2.0 to 80.0 µg/mL	0.5 to 80.0 µg/mL

Summary of Performance Testing

Limit of Quantitation (LOQ)

The limit of quantitation determines the lowest concentration which results in inter-assay precision at 7% CV or 0.7 µg/mL SD and bias to be within 10% or 1.0 µg/mL that has been measured over an extended period. The results demonstrate that the LOQ is 2.0 µg/mL and meets design acceptance criteria.

Precision

Phenobarbital samples tested for precision following a CLSI protocol. In the study, the total run %CV was less than or equal to 6.7% and meets design acceptance criteria.

Spike Recovery

Negative serum samples were spiked with phenobarbital at concentrations across the assay range. All of the samples recover within ±10% or ±1.0 µg/mL error of the HPLC results.

Method Comparison

Samples were tested in the Phenobarbital Assay and compared to HPLC. The assay correlated well with HPLC as follows: $y = 0.933x + 0.68$, $R = 0.9887$, $n=108$.

Matrix Comparison

The following matrices were tested and may be suitable for use in the Phenobarbital Assay: serum in glass, serum in plastic, serum separator tube (SST) in plastic, plasma with sodium fluoride/potassium oxalate in plastic, plasma with sodium heparin in plastic and glass, plasma with lithium heparin in plastic with or without gel, plasma with K3 EDTA in glass and plastic, plasma with K2 EDTA in plastic, and sodium citrate in plastic and glass.

Specificity

The assay showed minimal to no cross reactivity to other medications potentially administered with phenobarbital. The assay also showed minimal to no interference to endogenous substances up to the concentrations tested.

Linearity

Samples were tested to demonstrate linearity throughout the assay range. Results demonstrate that the assay performs in a linear fashion from 2.0 to 80 µg/mL.

Onboard Stability

Using the Abbott Architect *c*System, the reagents were stable onboard for up to 45 days.

Standard Curve Calibration Stability

Using the Abbott Architect *c*System, the standard curve calibration was stable for up to 14 days.

Reagent Shelf Life Stability

Studies showed that the reagents will be stable at 2-8°C for 24 months.

Conclusion

Substantial equivalence of the Phenobarbital Assay to the previously cleared Abbott Aeroset® Phenobarbital Assay (k993031) has been demonstrated through performance testing (Section 18) to verify that the device functions as intended and design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Microgenics Corp.
C/O Karen Lee, Regulatory Affairs Specialist
Thermo Fisher Scientific, Clinical Diagnostics Division
46360 Fremont Blvd
FREMONT CA 94538

Re: K123271
Trade/Device Name: Abbott Phenobarbital Assay
Regulation Number: 21 CFR 862.3660
Regulation Name: Phenobarbital test system
Regulatory Class: II
Product Code: DLZ
Dated: February 27, 2013
Received: March 18, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k123271

Device Name:
Abbott Phenobarbital Assay

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123271